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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,213	02/13/2002	Dominique Begon	F15026 US-CNT	9260

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EXAMINER

PULLIAM, AMY E

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 09/09/2003

/s/

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/075,213

Applicant(s)

BEGON ET AL.

Examiner

Amy E Pulliam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 11-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) Z.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Information Disclosure Statement, received by the Office January 30, 2003, as well as the Extension of Time and the Election, both received June 20, 2003.

Response to Election with Traverse

Applicant's election with traverse of Group I, and triamcinolone acetonide in Paper No. 9 is acknowledged. The traversal is on the ground(s) that in a search for the art of group I, art relating to the inventions of Group II and III would also be found. This is not found persuasive because processes of making, compositions, and apparatus claims are very distinct and are found in distinct classifications. Uncovering art for a process claim would not necessarily uncover art for a particular apparatus. There would be a serious burden on the examiner to search all three groups together.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-7, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,314,506 to Midler, Jr. *et al.* (hereafter Midler).

Midler teaches the use of jets to create impinging fluid jet streams and thereby achieve high intensity micromixing of the fluids prior nucleation in a crystallization process (column 4, lines 57-60). Midler also teaches that preferably the two jet streams are substantially diametrically opposed to each other (column 4, lines 63-65). Midler further teaches that the two fluids used in the invention can be of different solvent composition, one fluid being a solution of the compound to be crystallized in a suitable solvent or combination of solvents (feed solution) and the other fluid being a suitable solvent or combination of solvents capable of initiating that compound's precipitation from solution (anti solvent). Midler teaches that such solvents and antisolvents can include but are not limited to methanol, ethyl acetate, methylene chloride, acetonitrile, acetic acid, hexanes, ethers and water (column 5, lines 7-20). Midler also teaches that in order to obtain good results, the linear velocity in the jet nozzles should be at least about 5 meters/second, more preferably above 10 m/s, and most preferably between about 20 and 25 m/s. However, Midler states that the upper limit of linear velocity is only limited by the practical difficulties involved in achieving it (column 6, lines 50-57). Lastly, Midler teaches the use of much greater amounts of antisolvent as compared to the solution comprising the medicament (see examples).

Midler does not teach the velocity of the streams exceeding 30 m/s or 50 m/s. However, he does suggest that a higher velocity is desirable for this method, and that any limits on the upper limit of the velocity are only due to practical difficulties. This clearly suggests the use of velocities higher than 25 m/s. Furthermore, the examiner would like to point out Applicant's

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statement at page 5 , lines 1-5 of the specification. Applicant states, "The exact velocities to be used will depend on the nature of each of the medicament, solvent, and anti-solvent." Therefore, both Applicant and Midler recognize varying the velocity, depending on several factors, with a high velocity being ideal.

It is the position of the examiner that the teachings of Midler suggest the limitations of Applicant's instant claims. Midler teaches the same process to achieve the same purpose, small particles with high surface area and high bioavailability, without the need for milling. One would have been motivated, based on the teachings of Midler, to use as high a velocity as practically possible, based on Midler's advice to do so. The expected result would be a successful pharmaceutical formulation, as disclosed by Midler. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Midler, in view of US Patent 4,599,294 to Matsumoto *et al.*.

Midler is discussed above as teaching the same process as Applicant, for the same purpose, making particles.

Midler does not specifically teach the use of the solvent dimethylformamide. However, Midler teaches the use of that such solvents and antisolvents as methanol, ethyl acetate, methylene chloride, acetonitrile, acetic acid, hexanes, ethers and water (column 5, lines 7-20). Midler, however , teaches that this list is not exhaustive. It is the position the examiner that dimethylformamide is a known solvent in the pharmaceutical art. For reiteration of this point,

the examiner points to the teachings of Matsumoto *et al.* Matsumoto is relied upon for the teaching at column 10, lines 42-57, where a large list of known solvents is found, including such solvents as dimethylformamide, methylene chloride, and ethyl acetate. One of ordinary skill in the art would have been motivated to use any known solvent in the teachings of Midler, to achieve the desired purpose, particularly based upon Midler's statement that their list of solvents is not exhaustive. Furthermore, the selection of a material based on its suitability for its intended use is obvious absent a clear showing of unexpected results attributable to the Applicant's specific selection. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Midler in view of US Patent 3,897,779 to Hansen.

Midler is discussed above as teaching the same process as Applicant, for the same purpose, making particles.

Midler does not specifically teach the use of the active agent triamcinolone acetonitrile. However, Midler clearly teaches that many active agents can be used with their invention (column 5, lines 55-57). A medicament which would be particular useful in the Midler invention is one where small particles with high surface area, improved stability and purity are desired.

Hansen is relied upon for the teaching that triamcinolone acetonide is used in inhalation therapy, where high surface area, small particles, and improved stability and purity are greatly desired. Therefore, triaminolone acetonide would be an excellent medicament for the invention of Midler. Furthermore, it is the position of the examiner that the use of a particular active agent,

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in a known process, absent a showing of unexpected results, does not impart patentability. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. E. Pulliam
Patent Examiner
September 6, 2003

THURMAN K. PAGE, J.D.
SUPERVISORY PATENT EXAMINER